

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:)	Group Art Unit: 1743
)	
BRUCE W. ANDERSON <i>et al.</i>)	Examiner: Ramdhanie, B.
)	
Serial No. 10/763,449)	Atty. Docket No. GP106-11.DV4
)	
Filed: January 23, 2004)	Confirmation No. 9247
)	
For: METHOD FOR REMOVING A)	Filed via EFS Web
FLUID SUBSTANCE FROM A)	
COLLECTION DEVICE)	

PRE-APPEAL BRIEF REQUEST FOR REVIEW

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Commissioner for Patents
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Sir:

In response to the Advisory Action delivered on April 21, 2008, Applicants identify below clear errors in the Examiner's claim construction analysis, bases for patentability rejections, and unsupported conclusions tied to newly cited references in the above-captioned application.

Improper Claim Construction

Claim 1 of the present invention recites an automated method for removing the contents of a collection device which includes, *inter alia*, puncturing a cap of the collection device with a fluid transfer device, moving the fluid transfer device into a fluid-holding vessel of the collection device, drawing a fluid substance contained in the vessel into the fluid transfer device, and then removing the fluid transfer device from the collection device. In one embodiment of the invention recited in claim 3, the fluid transfer device is a plastic pipette tip. McGregor *et al.* (U.S. Pat. No. 4,808,381), the primary reference cited by the Examiner, discloses the use of a cannula (30) to create an opening in a closure (18). After creating the opening (18), independent suction members (14, 14') having stems (24, 24') are inserted through the cannula (30) and contact different layers (20a, 20) contained

in a receptacle (10). Thus, the puncturing step and the drawing and removing steps of McGregor are performed by distinct devices, which the Examiner now appears to acknowledge.

Notwithstanding, the Examiner asserts in paragraph 1 of the Advisory Action that claim 1 uses the transitional term “comprising” and, therefore, claim 1 “may contain more steps and it may contain other devices in conjunction with the method.” The Examiner goes on to conclude that “[i]t is reasonable to think that more than one fluid transfer device may be used” in the claimed method. Applicants agree that the claim language permits additional steps and the use of devices that are not specifically recited in the claims, but the claim language unequivocally requires that each of the recited steps be performed with a single fluid transfer device, which is not taught by the cited reference. While claims using open-ended transitional terms may embrace elements that are not specifically recited in the claims, such terms do not permit recited elements to be altered or eliminated from the claims. Thus, the Examiner’s conclusion that Applicants use of the transitional term “comprising” in the claims alters the requirement that the puncturing, drawing and removing steps all be performed with the same fluid transfer device violates the clear meaning of the claims. *See Genentech, Inc. v. Chiron Corp.*, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) (“Comprising” is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.) (Emphasis added.)

As the Examiner’s patentability arguments require an impermissible construction of the claims permitting the puncturing, drawing and removing steps to be performed by a combination of devices, Applicants respectfully submit that the Examiner’s patentability rejections should be withdrawn for the reasons elaborated in their Request for Reconsideration dated April 1, 2008.

Impermissible Modification of the Prior Art

The Examiner further argues in paragraph 3 of the Advisory Action that the cannula (30) disclosed by McGregor could be modified to include a bulb or it could be attached to a pipettor. This suggestion, however, would require an impermissible change to the principal of operation of the cannula (30) disclosed by McGregor. *See* MPEP § 2143.01 (proposed modification cannot

render the prior art unsatisfactory for its intended purpose or change the principle of operation of a reference). McGregor, for example, discloses that the cannula (30) is formed of a rigid plastic for piercing a closure (18), while the suction members (14, 14') are constructed of a flexible plastic material to permit the stems (24, 24') to bend toward the periphery of a receptacle. *See* McGregor at col. 2, lines 31-38 and 55-59; and col. 4, lines 5-9, 16-20 and 32-34. In addition, if McGregor's cannula (30) was modified to include a bulb or if it was attached to a pipettor, as suggested by the Examiner, then it would be incapable of performing one of its stated functions, which is to maintain a vent to the atmosphere for the inside of the receptacle (10) after the cannula (30) has penetrated a self-sealing stopper (18). *See* McGregor at col 4, lines 8-9 and 52-55. Thus, if the cannula (30) of McGregor was modified in the manner proposed by the Examiner, then the cannula (30) would be incapable of performing the penetrating, drawing and removing steps of McGregor's method.

Incomplete Response

In the Advisory Action, the Examiner does not address the further limitations of step b) of independent claim 1 ("pausing movement of the fluid transfer device prior to contacting a fluid substance in the vessel") and step c) of independent claim 21 ("entering the collection device with the fluid transfer device moving at a second speed"). These steps are neither anticipated by nor obvious in view of the teachings of McGregor, as the "transfer device" of McGregor is a cannula (30) that is used to create an opening in a closure (18), but it is not used -- nor is it designed to be used -- to enter a receptacle and draw a fluid substance contained therein. The Examiner previously argued that it would have been obvious to introduce a pause step to allow an operator to visually confirm that the fluid transfer device has passed through the cap before proceeding with the removal of the fluid, and to alter the speed of the fluid transfer device to minimize exposure of the operator to fluid or fluid vapor. *See* paragraphs 3 and 15 of the Office Action delivered on September 20, 2007. Given the Examiner's rationale, it was never explained what motivation there would have been for including these additional steps in an automated procedure, as claimed.

Piecemeal Examination

According to MPEP § 707.07(g), an examiner should ordinarily reject each claim on all valid grounds available, avoiding undue multiplication of references. Here, the Examiner maintains the patentability rejections in view of all previously cited references and now cites an additional eight references to “support the fact that the claims of the instant application are not novel.” The Examiner provides no explanation of *how* these references affect the patentability of the presently claimed invention, nor does the Examiner identify the supposedly relevant sections of these references. Further, not only does this represent an undue multiplication of references, but citing these references as “back-up” in an Advisory Action does not provide Applicants with a meaningful opportunity to respond to the Examiner’s undisclosed reasons for relying upon these references. *See* MPEP § 707.07(d) (omnibus rejections of claims are not informative and should be avoided).

For the reasons set forth above and in their Request for Reconsideration, Applicants submit that the presently pending claims are fully patentable in view of the cited references.

Please charge the fees due in connection with this Request to Deposit Account No. 07-0835 in the name of Gen-Probe Incorporated.

Respectfully Submitted,

Date: May 1, 2008

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